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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/811,933	03/19/2001	Marc D. Better	11051US03 / 200-85	9646

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EXAMINER

MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/17/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/811,933

Applicant(s)

BETTER, MARC D.

Examiner

Terry A. McKelvey

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 6,7,10-17,23,24,31,32,40,41,48 and 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,9,18-22,25-30,33-39,42-47,50 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 6) ☐ Other:

Art Unit: 1636

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group III, claims 1-5, 8-9, 18-22, 25-30, 33-39, 42-47, and 50-51 in Paper No. 9, filed 10/25/02 is acknowledged.

Claims 6-7, 10-17, 23-24, 31-32, 40-41, and 48-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in Paper No. 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5, 8-9, 18-22, 25-30, 33-39, 42-47, and 50-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

Art Unit: 1636

relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method for producing a recombinant protein, etc, comprising introducing an expression vector comprising an inducible promoter controlling the expression of a protein product into a bacterial host cell that is genetically deficient in at least one system for active transport of an inducer of the promoter and inducing expression of a product with the inducer. The method claims are genus claims because they comprise the use of bacterial host cells which comprise a genus: the bacterial host cell is drawn to any bacterial host cell that is deficient in any active transport system for an inducer that controls the expression of a protein product encoded by an expression vector introduced into the cell, and use of the corresponding inducible promoter that is controlled by the inducer. Thus, the host cell claimed in the method encompasses many different host cells, inducers, transport systems, and inducible promoters in addition to the single type of host cell, inducer, deficient transport systems, and inducible promoter actually set forth in the application.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the

Art Unit: 1636

genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In the instant case, the only factors present in the claims are a description of a single type of host cell and transport system that is deficient, drawn to an E. coli host cell that is deficient in arabinose transport (applicant elected that the deficiency is in both of the only known and described transport systems for arabinose, araE and araFGH). The only inducible promoter taught for this system is the araB promoter, induced by arabinose. There is no description in the specification of the inducer, host cells, deficient transport system(s), and inducible promoter for any other system that the application describes as functioning as claimed in the instant application. Accordingly, in the absence of sufficient recitation of all of the distinguishing characteristics needed for function of the broad genus as claimed, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in

Art Unit: 1636

possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*."

(See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polynucleotides, and therefore conception is not achieved until reduction of practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Ravel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGFs were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the claimed methods drawn to the single combined system taught by the application: arabinose as the inducer, *E. coli* as the host cell which is deficient in both

Art Unit: 1636

araE and araFGH genes (elected), and araB as the inducible promoter, but not the full breadth of the claims, meet the written description provision of 35 USC 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112, first paragraph is severable from its enablement provision (see page 1115).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1, the use of "into the host cell" in the fifth line of claim 1 renders the claim vague and indefinite because the expression vector was already indicated as being introduced into the bacterial host cell in line 4. Amending the claim to delete this redundant phrase would be remedial.

Regarding claim 9, there is no positive antecedent basis for "the induced host cells".

Art Unit: 1636

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 8-9, 18, 22, 25-26, 30, 33-35, 39, 42-43, 47, and 50-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hahn et al (applicant reference indicated as AA1 by the examiner in the IDS, paper no. 6).

Hahn et al teach introduction of an expression vector which contains a B-galactosidase gene operably linked to the araC promoter into E. coli host cells deficient in both the araE and araFGH arabinose transport systems. This reference teaches producing recombinant B-galactosidase by culturing the cells and inducing the B-galactosidase gene with arabinose (Materials and Methods and page 598 - page 599, column 2). The protein product was recovered from the induced cells as part of the measurement of the product's activity (i.e., the amount of the product was measured). Because more B-galactosidase was produced in the presence versus the absence of the inducer, the amount of inducer used appears to be effective for synchronous induction,

Art Unit: 1636

bacterial cell growth inhibition by the inducer appears to be reduced, and the yield of the protein product was increased by the method.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014.

NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

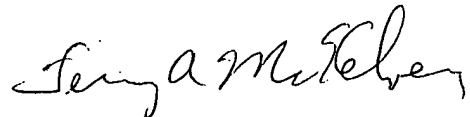
Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be

Art Unit: 1636

responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.
Primary Examiner
Art Unit 1636

January 13, 2003